

U.S.S.N. 09/658,390  
Filed: September 8, 2000  
AMENDMENT AND RESPONSE TO OFFICE ACTION

### Remarks

Claims 38-49 are pending. Claims 47 has been amended. Claim 47 has been amended to specify that the molecule is a monomer. Support for this amendment can be found in the specification at least at page 14, lines 1-10.

### Rejection Under 35 U.S.C. § 112, second paragraph

Claims 47-49 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The claims have been amended to identify the molecule as a monomer. Therefore claims 47-49, as amended, are definite.

### Rejection Under 35 U.S.C. § 103

Claims 38-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,726,250 to Zajackowski ("Zajackowski '250"), in view of U.S. Patent No. 5,410,016 to Hubbell ("Hubbell"). Claims 38-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zajackowski '250, in view of WO 98/12243 to Jarrett *et al.* ("Jarrett"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

### *The Legal Standard*

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177

U.S.S.N. 09/658,390

Filed: September 8, 2000

AMENDMENT AND RESPONSE TO OFFICE ACTION

(C.C.P.A. 1967), *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). In rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that: (i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention would have a reasonable likelihood of success. *In re Dow Chemical Company*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

The prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. *In re Geiger*, 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); *In re Lalu and Foulletier*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). The Court of Appeals for the Federal Circuit warned that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994 at 999 (Fed. Cir. 1999). The "question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *WMS Gaming, Inc. v International Game Technology*, 184 F.3d 1339 at 1355 (Fed. Cir. 1999). "[T]he showing must be clear and particular." *In re Dembiczak*, 175 F.3d 994 at 999 (Fed. Cir. 1999). Although with the answer in hand, the

U.S.S.N. 09/658,390

Filed: September 8, 2000

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

"solution" now appears obvious, that is not the test. The references must themselves lead those in the art to what is claimed. And in this case, there is simply no such teaching.

***Zajackowski '250***

Zajackowski '250 discloses pressure-sensitive adhesive materials formed from hydrophilic macromers and water soluble monomers (col. 3, lines 24-27). Zajackowski '250 uses a macromer that is different than the macromer defined by the present claims; it does not contain hydrophobic regions in addition to hydrophilic regions and at least two polymerizable groups. Zajackowski '250 selects the macromer and monomer to produce materials which are pressure sensitive adhesives. Zajackowski '250 does not form a gel upon polymerization. For example, in one embodiment, after polymerization and crosslinking, they are applied to a backing material in the form of a liquid (col. 8, lines 6-9). In another embodiment, a blowing agent is added and they produce a foam (col. 9, lines 1-9).

***Hubbell***

Hubbell discloses hydrogels formed of polymerized macromers. The hydrogels may contain small amounts of a monomer, such as triethanol amine, which serves as a crosslinker during the polymerization reaction (see col. 14, lines 38-45). These hydrogels are not pressure-sensitive materials. The hydrogels contain a lot of water and minimal solids. Table 7 recites the amount of water that is absorbed by various gels. The amount of water in these gels ranges from 82% (wt/wt) -94% (wt/wt).

U.S.S.N. 09/658,390  
Filed: September 8, 2000  
AMENDMENT AND RESPONSE TO OFFICE ACTION

***Jarrett***

Jarrett discloses hydrogels that are formed from macromers containing at least one carbonate or dioxanone group, at least one water soluble block, and at least one polymerizable group (abstract). Jarrett uses a photoinitiation system, which includes triethanol amine, to polymerize the macromer (see Example 3). Optionally, Jarrett includes a very small amount of a comonomer, such as vinyl caprolactam (4000 ppm) (page 39, lines 16-17). The resulting polymers are used as tissue sealants and coatings on tissue and medical devices (see page 7, lines 10-16; page 32, lines 1-18). They are not pressure-sensitive materials. These materials absorb a lot of water, are very elastic and have a low modulus (*see e.g.* Example 8, page 46, lines 1-14), had a compressive modulus of only 32.4 kPa (0.0324 MPa) (page 47, Table 1)).

***The combined references***

There is no teaching or suggestion in the references to combine them as the Examiner has done. Zajaczkowski '250 discloses different macromers than either Hubbell or Jarrett. Zajaczkowski '250 is directed at forming polymers with different properties from the types of polymers formed by either Hubbell or Jarrett. Zajaczkowski '250 specifically selects monomers and hydrophilic macromers to form adhesive, pressure sensitive materials, which are attached to synthetic materials to allow these materials to adhere to wound surfaces. Upon polymerization, Zajaczkowski '250's macromers and monomers do not form a gel. In contrast, Hubbell and Jarrett are directed at using macromers that contain hydrophilic and hydrophobic regions to form gels upon polymerization. Further, Hubbell and Jarrett polymerize macromers with very small

U.S.S.N. 09/658,390

Filed: September 8, 2000

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

quantities of monomers that act as crosslinkers. Neither Hubbell nor Jarrett produce materials with the properties desired by Zajackowski '250. Therefore one of ordinary skill in the art would not substitute the hydrophilic macromers in Zajackowski '250 with the macromers in Hubbell or Jarrett. Thus, the claimed compositions are not obvious over Zajackowski '250 in view of Hubbell and/or Jarrett.

**Claim Objections**

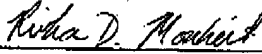
Claims 47-49 were objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form. Applicants respectfully traverse this objection to the extent that it is applied to the claims as amended.

Claim 47 has been amended to refer to a monomer, and further defines the monomer of claim 38. Therefore claims 47-49 are in proper dependent form.

U.S.S.N. 09/658,390  
Filed: September 8, 2000  
**AMENDMENT AND RESPONSE TO OFFICE ACTION**

Allowance of claims 38-49, as amended, is respectfully solicited.

Respectfully submitted,

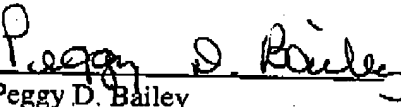
  
\_\_\_\_\_  
Rivka D. Monheit  
Reg. No. 48,731

Date: November 3, 2003

**HOLLAND & KNIGHT LLP**  
One Atlantic Center, Suite 2000  
1201 West Peachtree Street  
Atlanta, Georgia 30309-3400  
(404) 817-8514  
(404) 817-8588 (Fax)

**Certificate of Facsimile Transmission**

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, November 3, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

  
\_\_\_\_\_  
Peggy D. Bailey

Date: November 3, 2003

# 1216512\_v1

1216512v1

10

FTT 126  
077637/00017